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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,076	10/03/2001	John A.T. Young	960296.97745	9060

7590

04/10/2003

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 04/10/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/970,076

Applicant(s)

YOUNG ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-9, 11-13 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9, 11-13 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. Applicants' amendment filed January 13, 2003 is acknowledged and has been entered. Claims 1-4 and 14-18 have been canceled. Claims 5 and 19 have been amended. It appears that claim 11 has been amended, however "(Amended)" does not appear before the claim as it does in amended claims 5 and 19. Clarification is requested. Claims 5-9, 11-13 and 19-21 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 5-9 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5, lines 1-2 recite "the polynucleotide encoding a soluble polypeptide selected from the group consisting of a PA-binding fragment of ... SEQ ID NO:6" for example. Further, in claim 5, at lines 5-6 the claim recites "the polynucleotide being unable to encode a polypeptide selected from the group consisting of SEQ ID NO: 6." It is not clear if the polynucleotide encodes the polypeptide or not. The same is true for SEQ ID NO:8 and SEQ ID NO:10. drop

4. It is noted that Applicants are entitled to the filing date of 10/3/01, not the filing date of the provisional application 60/251481 filed 12/5/00. The provisional application is not in compliance with the CRF Rules. If Applicants desire *Keep* priority back to the provisional application, Applicants should direct the Examiner to the exact support, by page and sequence number, in the specification of the provisional application. Further, the provisional application is not available to the Examiner at present.

5. The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other *drop* form of browser-executable code, see page 9 for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

6. Claims 5-7, 9, 11-13, and 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by WO200134626-A1 (Accession #:AAD5303) , Accession # BC012074 from NCBI. *Keep*

The prior art discloses a polynucleotide sequence that has 99.7% similarity/identity with the claimed SEQ ID NO: 1. The prior art discloses the claimed polynucleotide sequence of SEQ ID NO: 1 or a fragment thereof. The prior art discloses methods for producing the polypeptide encoded by the polynucleotide sequence.

Applicants have asserted that neither sequence anticipates the claims as amended, a polynucleotide that encodes a soluble polypeptide. Applicant's arguments filed January 13, 2003 have been fully considered but they are not persuasive. The sequences (accession numbers) disclose both the nucleotide sequences (SEQ ID NO:1) and amino acid sequences (SEQ ID NO:2). With regard to the polypeptide being soluble, it would appear that this is an inherent property since the same sequences are disclosed.

The claimed invention is anticipated by the prior art. The prior art anticipates the claimed invention by disclosing the polynucleotide having the same or similar characteristics as claimed. The polynucleotide in the prior art is believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polynucleotide, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polynucleotide of the prior art is evidenced to meet the limitations of the claimed polynucleotide, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polynucleotide of the prior art does not possess the same material structural and functional characteristics of the claimed polynucleotide) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claims 5-9, 11-13, and 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Bradley et al 2001 (Nature, 414(6860):225-229).

Bradley et al discloses a cellular receptor for the anthrax toxin, that it binds the protective antigen (abstract), and the sequence of the receptor (figure 2; see also Accession #: AF21380). Bradley et al discloses methods of cloning sequencing and producing the polypeptide encoded by the polynucleotide sequence (p. 228, col. 2). Bradley et al also references GenBank accession code BC012074 (p. 228). The prior art discloses SEQ ID NO: 1 or a fragment thereof. *drop*

Applicant's arguments filed January 13, 2003 have been fully considered but they are not persuasive. Applicants have asserted that Bradley et al, 2001 is research described in the pending patent application. Applicants state that should the so-called In re Katz declaration be required, applicants stand ready to provide such a declaration. It is noted that the declaration is required and the rejection will be maintained until such declaration has been properly filed in the pending patent application.

8. Claims 5-9 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by St. Croix et al (2000).

The prior art discloses the polynucleotide sequence as set forth in claimed SEQ ID NO: 1 or a fragment thereof (see accession # AF279145). *Keep*

Applicants have asserted that neither sequence anticipates the claims as amended, a polynucleotide that encodes a soluble polypeptide. Applicant's arguments filed January 13, 2003 have been fully considered but they are not

persuasive. The sequences (accession numbers) disclose both the nucleotide sequences (SEQ ID NO:1) and amino acid sequences (SEQ ID NO:2). With regard to the polypeptide being soluble, it would appear that this is an inherent property since the same sequences are disclosed.

The claimed invention is anticipated by the prior art. The prior art anticipates the claimed invention by disclosing the polynucleotide having the same or similar characteristics as claimed. The polynucleotide in the prior art is believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polynucleotide, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polynucleotide of the prior art is evidenced to meet the limitations of the claimed polynucleotide, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polynucleotide of the prior art does not possess the same material structural and functional characteristics of the claimed polynucleotide) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

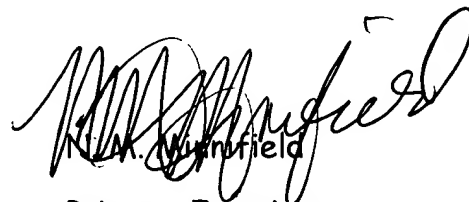
9. No claims are allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'N. M. Minnifield', is written over a faint, rectangular stamp that also contains the name 'N. M. Minnifield'.

Primary Examiner

Art Unit 1645

NMM

April 3, 2003